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EPAExecSec <EPAExecSec@epa.gov>
FW: Petition to Include a Soil Health Endpoint in Pesticide Ecological Risk Assessment
To: "CMS.OEX" <cms.oex@epa.gov>

From: Nathan Donley <NDonley@biologicaldiversity.org>
Sent: Thursday, May 20, 2021 11:14 AM
To: Regan, Michael <Regan.Michael@epa.gov>; Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Goodis, Michael <Goodis.Michael@epa.gov>; Matuszko, Jan <Matuszko.Jan@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Echeverria, Marietta <Echeverria.Marietta@epa.gov>; Lori Ann Burd <LABurd@biologicaldiversity.org>; Nathan Donley <NDonley@biologicaldiversity.org>
Subject: Petition to Include a Soil Health Endpoint in Pesticide Ecological Risk Assessment

Dear Administrator Regan, Principal Deputy Assistant Administrator Freedhoff, and Acting Director Messina,

Please find attached the Center for Biological Diversity and Friends of the Earth’s petition to strengthen EPA’s pesticide risk assessment process for terrestrial invertebrates by including further data requirements and conducting a separate analysis to characterize risk to soil ecosystems. Also attached is a separate letter of support signed by 67 organizations.

Developing a regulatory framework that incorporates a soil health analysis into pesticide testing will have a beneficial impact on food production, water and air quality, nutrient cycling, pest and disease outbreaks, remediation of pollutants, resilience to climatic events such as droughts and fires, carbon sequestration and biodiversity.

A soil health endpoint not only meets every single inclusion criterion for ecological risk assessment under the agency’s current guidance, but it is also necessary for the EPA to comply with its statutory requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

A hard copy of the petition and letter of support has also been sent, via certified mail, to the Office of Pesticide Programs (7501P), 1200 Pennsylvania Ave. NW., Washington, DC 20460.

Please contact Lori Ann Burd or myself with any questions or concerns regarding this petition. We look forward to your response.

Nathan Donley, Ph.D

Environmental Health Science Director

Center for Biological Diversity

971-717-6406

ndonley@biologicaldiversity.org

CC

Michael Goodis, Acting Deputy Director of Programs goodis.michael@epa.gov

Jan Matuszko, Acting Director Environmental Fate and Effects Division matuszko.jan@epa.gov

Elissa Reaves, Acting Director Pesticide Re-Evaluation Division reaves.elissa@epa.gov

Marietta Echeverria, Acting Director Registration Division echeverria.marietta@epa.gov

Lori Ann Burd, Environmental Health Program Director and Senior Attorney at the Center for Biological Diversity
laburd@biologicaldiversity.org

May 20, 2021

Sent Via Electronic and Certified Mail

Michael Regan, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Mail Code: 1101A
Washington, DC 20460
regan.michael@epa.gov

Michal Ilana Freedhoff, Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave. NW
Mail Code: 7101M
Washington, DC 20460
freedhoff.michal@epa.gov

Edward Messina, Acting Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Mail Code: 7501P
Washington, DC 20460
messina.edward@epa.gov

Re: Petition for Rulemaking to Implement a Soil Health Endpoint in EPA's Ecological Risk Assessment for Pesticides

Dear Administrator Regan, Principal Deputy Assistant Administrator Freedhoff, and Acting Director Messina,

Pursuant to the right to petition the government provided in the First Amendment to the U.S. Constitution¹ and the Administrative Procedure Act,² the Center for Biological Diversity and Friends of the Earth U.S. hereby petition the U.S. Environmental Protection Agency to strengthen its pesticide risk assessment process for terrestrial invertebrates by including further data requirements and conducting a separate analysis to characterize risk to soil ecosystems. Soil

¹ See U.S. Const. Amend. I; see also *United Mine Workers v. Ill. State Bar Ass'n*, 389 U.S. 217, 222 (1967) (explaining that the right to “petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights”).

² See 5 U.S.C. § 553(e).

health is the building block of life and healthy agricultural practices. To continue to overlook pesticide impacts to soil health is to rob future generations of the opportunity to grow healthy and nutritious food.

Developing a regulatory framework that incorporates a soil health analysis into pesticide testing will have a beneficial impact on food production, water and air quality, nutrient cycling, pest and disease outbreaks, remediation of pollutants, resilience to climatic events such as droughts and fires, carbon sequestration and biodiversity.

Petitioners incorporate by reference, in full, all studies and documents cited in this petition.

This petition seeks two changes:

- 1) EPA's Pesticide Assessment Guidelines, codified at 40 C.F.R. 152 and 158, which set forth the data requirements and protocols to register a pesticide³ should be amended to require a soil health analysis and incorporate additional data requirements necessary to estimate risk to soil health.

Specifically, petitioners seek to add the following paragraph to 40 C.F.R. 152.112:

“(i) In accordance with paragraph (e) of this section, the Agency must account for the harms to soil organisms and the ecosystem services they provide.”

Additionally, petitioners seek to add six required tests for any outdoor use of a pesticide. The following data requirements should be added to the table in 40 C.F.R. 158.630(d):

- Sublethal effects to the earthworm
- Sublethal effects to the springtail
- Sublethal effects to the mite
- Effects on nitrogen transformation
- Sublethal effects to an isopod species
- Effects on mycorrhizal fungi

- 2) In order to effectively incorporate the above regulation changes into its pesticide approval process, the EPA should develop Soil Health Guidelines to provide guidance on how the agency can comply with its amended regulations.

³ 40 C.F.R. § 158.70; *Lucas v. Bio-Lab, Inc.*, 108 F. Supp. 2d 518, 527 (E.D. Va. 2000).

These changes would effectively create a “Soil Health” endpoint in EPA’s ecological risk assessment for pesticides, very similar to how the agency currently assesses risk to pollinators or aquatic invertebrates.

Executive Summary

Soil is synonymous with life. Just a bucket full of healthy soil has more living organisms than there are human beings on this planet. This subterranean web of life is constantly working - filtering our water, preventing flooding, recycling nutrients, preventing disease outbreaks, and helping regulate the Earth’s temperature. Additionally, 95% of the world’s food comes either directly or indirectly from soil – so it’s not only necessary for our quality of life, but our entire existence.

The EPA estimates that 50-100% of agriculturally-applied pesticides – chemicals designed to kill life – end up in the soil. Furthermore, overuse of chemical inputs like pesticides in agriculture has been identified as the most impactful driver of soil biodiversity loss in the last decade. This makes it absolutely imperative that EPA estimate the risk pesticides pose to soil organisms and the ecosystem services they provide.

This does not happen under current practice. At present, EPA assesses risk to all soil organisms using the European honey bee as a surrogate model. The agency simply cannot accurately estimate exposure and toxicity to soil organisms from a species that may go its entire life without even touching the soil.

On May 4th, 2021, petitioners published a peer reviewed paper, the most comprehensive review ever conducted of pesticide impacts on soil, which found harm to beneficial soil invertebrates in 71% of cases analyzed. We can no longer pretend that pesticides do not significantly affect soil health nor that the consequences for agriculture and a livable climate are *de minimus*.

Therefore, we are petitioning the EPA to update its regulations to include additional testing requirements and a separate analysis for soil organisms. In these updates, effects to soil health would be inferred through tests on at least six species or processes that can provide a readout of the ecosystem services provided by agricultural soils. This will allow the agency’s scientists to quantify, analyze and mitigate risk to soil ecosystems from pesticides.

A soil health endpoint not only meets every single inclusion criterion for ecological risk assessment under the agency’s current guidance, but it is also necessary for the EPA to comply with its statutory requirements under FIFRA. Therefore, EPA must account for harms to soil organisms in its pesticide risk assessments for any pesticide that has the potential to contaminate soil.

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I. Petitioner Information

The Center for Biological Diversity is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. The Center has more than 1.7 million members and online activists dedicated to the protection and restoration of endangered species and wild places. For over 30 years, the Center has worked to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life. The Center's Environmental Health Program aims to improve pesticide regulation in order to reduce the threat of toxic pollution, including the harms of pesticides to people, the environment as a whole, and imperiled species in particular.

Friends of the Earth U.S., founded by David Brower in 1969, is the U.S. voice of the world's largest federation of grassroots environmental groups, with a presence in 75 countries. Friends of the Earth works to defend the environment and champion a more healthy and just world. Through the organization's nearly 50-year history, it has provided crucial leadership in campaigns resulting in landmark environmental laws, precedent-setting legal victories and groundbreaking reforms of domestic and international regulatory, corporate and financial institution policies.

The petitioners are significantly harmed by EPA's current ecological risk assessment process because it ignores threats to soil health, soil organisms, and biodiversity. Accordingly, amending 40 C.F.R. 152.112 and 40 C.F.R. 158.630(d) to include a soil health analysis and testing requirements, and creating a Soil Health guidance document, would better protect humans and the environment and aid the agency in carrying out its mission.

II. Soil Health is Critical to Life on Earth

Soil is a basic and precious natural resource and the foundation of life on Earth. Soils are incredibly complex and important ecosystems that are estimated to contain roughly a quarter of Earth's biological diversity.⁴ Healthy soil is teeming with life, with an estimated 10-100 million organisms present in a single handful.⁵ Thousands of species of soil invertebrates and microorganisms provide essential ecosystem services necessary for agricultural sustainability and ecological functioning, including carbon sequestration.

⁴ Ram, Dr. R. L. ed. (2019). *Current Research In Soil Fertility*. 1st ed. AkiNik Publications
doi:10.22271/ed.book.437.

⁵ Ramirez, K. S., Döring, M., Eisenhauer, N., Gardi, C., Ladau, J., Leff, J. W., et al. (2015). Toward a global platform for linking soil biodiversity data. *Front. Ecol. Evol.* 3. doi:10.3389/fevo.2015.00091.

1. Food and Agriculture

It is estimated that 95% of the world's food comes either directly or indirectly from soil.⁶ It can take between 100 – 1,000 years to produce 1 cm of fertile topsoil, but only a matter of a few years to lose it.⁷ Conventional farming practices can deplete soil ecosystems through agrichemical use, monocropping and tillage, leading to reduced productivity and crop yield.

Investments in healthy soil that improve the health, yield, and profitability of agriculture are increasingly being adopted around the world. It is estimated that sustainable soil management could increase food production by 58%.⁸ Maintaining healthy soils is absolutely essential to ensuring robust and productive agriculture in the U.S. and ensuring a supply of healthy and nutritious food for future generations.

2. Ecosystem Services and Biodiversity

Healthy soil refers to the soil's ability to sustainably deliver the ecosystem services necessary for the quality of life on this planet – services that are made possible by the diversity and abundance of soil organisms.^{9,10} A typical functional soil community is comprised of vertebrate species, such as burrowing mammals or reptiles, hundreds to thousands of invertebrate species per square meter of soil, and an abundance of microorganisms including thousands of fungal and bacterial taxa.^{11,12}

The health and diversity of soil organisms is the key to agricultural sustainability, enabling ecosystem functioning that can perpetuate important soil processes like soil structure maintenance, nutrient cycles, carbon transformation, and the regulation of pests and

⁶ Food and Agriculture Organization of the United Nations. Healthy soils are the basis for healthy food Production. 2015. Available here: <http://www.fao.org/3/i4405e/i4405e.pdf>.

⁷ European Commission. News: Soil matters for our future. December 5, 2019. Available here: https://ec.europa.eu/info/news/soil-matters-our-future-2019-dec-05_en.

⁸ Food and Agriculture Organization of the United Nations. Healthy soils are the basis for healthy food Production. 2015. Available here: <http://www.fao.org/3/i4405e/i4405e.pdf>.

⁹ Kibblewhite, M. G., Ritz, K., & Swift, M. J. (2008). Soil health in agricultural systems. *Philosophical transactions of the Royal Society of London. Series B, Biological sciences*, 363(1492), 685–701. <https://doi.org/10.1098/rstb.2007.2178>.

¹⁰ Adams, G. A., & Wall, D. H. (2000). Biodiversity above and below the surface of soils and sediments: Linkages and implications for global change. *BioScience*, 50(12), 1043. [https://doi.org/10.1641/0006-3568\(2000\)050\[1043:BAABTS\]2.0.CO;2](https://doi.org/10.1641/0006-3568(2000)050[1043:BAABTS]2.0.CO;2).

¹¹ Bardgett, R. D., & Van der Putten, W. H. (2014). Belowground biodiversity and ecosystem functioning. *Nature*, 515(7528), 505–511. doi:10.1038/nature13855.

¹² Singh, J., Schädler, M., Demetrio, W., Brown, G. G., and Eisenhauer, N. (2019). Climate change effects on earthworms - a review. *SOIL Org.* 91, 114-138-114–138. doi:10.25674/so91iss3pp114.

diseases.^{13,14,15} Humans depend on soil ecosystem services such as waste recycling, water storage and filtration, nutrient distribution to crops and forests, and regulation of the Earth's temperature and greenhouse gasses.

Soil ecosystem services have been reduced by approximately 60% due to the loss of soil biodiversity caused mainly by land conversion and agricultural intensification concomitant with increased agrichemical use.^{16,17,18} Up to 40% of the world's insect species are threatened with extinction over the next few decades – including insects that depend on soil for their life cycle, like dung beetles and the vast majority of native bee species, which are ground-nesting.¹⁹ Among the major driving factors of widespread insect harm are habitat loss due to agricultural intensification and pollution, primarily from synthetic agricultural pesticides and fertilizers.²⁰

3. Carbon Sequestration and Climate Resilience

Soils store the largest amount of terrestrial carbon on Earth.²¹ Soil sequesters and retains carbon from the atmosphere, and building soil health increases carbon sequestration. Nationally, agricultural soils have the capacity to sequester 250 million metric tons of CO₂ from the atmosphere.²² The ability of soil to capture and sequester carbon is intrinsically linked to its health and the proper functioning of soil organisms.

Farmers are already dealing with the impacts of climate change, which has resulted in the loss of billions of dollars of crops due to drought, heat, hot wind, extreme rainfall, flooding, and other

¹³ Balvanera, P., Pfisterer, A. B., Buchmann, N., He, J.-S., Nakashizuka, T., Raffaelli, D., et al. (2006). Quantifying the evidence for biodiversity effects on ecosystem functioning and services: Biodiversity and ecosystem functioning/services. *Ecol. Lett.* 9, 1146–1156. doi:10.1111/j.1461-0248.2006.00963.x.

¹⁴ Kibblewhite, M. G., Ritz, K., and Swift, M. J. (2008). Soil health in agricultural systems. *Philos. Trans. R. Soc. B Biol. Sci.* 363, 685–701. doi:10.1098/rstb.2007.2178.

¹⁵ Chagnon, M., Kreutzweiser, D., Mitchell, E. A. D., Morrissey, C. A., Noome, D. A., and Van der Sluijs, J. P. (2015). Risks of large-scale use of systemic insecticides to ecosystem functioning and services. *Environ. Sci. Pollut. Res.* 22, 119–134. doi:10.1007/s11356-014-3277-x.

¹⁶ Díaz, S., Fargione, J., Iii, F. S. C., and Tilman, D. (2006). Biodiversity Loss Threatens Human Well-Being. *PLOS Biol.* 4, e277. doi:10.1371/journal.pbio.0040277.

¹⁷ Singh, J., Schädler, M., Demetrio, W., Brown, G. G., and Eisenhauer, N. (2019). Climate change effects on earthworms - a review. *SOIL Org.* 91, 114-138-114–138. doi:10.25674/so91iss3pp114.

¹⁸ Veresoglou, S. D., Halley, J. M., and Rillig, M. C. (2015). Extinction risk of soil biota. *Nat. Commun.* 6. doi:10.1038/ncomms9862.

¹⁹ Sánchez-Bayo, F., and Wyckhuys, K. A. G. (2019). Worldwide decline of the entomofauna: A review of its drivers. *Biol. Conserv.* 232, 8–27. doi:10.1016/j.biocon.2019.01.020.

²⁰ *Id.*

²¹ Minasny, B., McBratney, A. B., Malone, B. P., Wheeler, I. (2013). Chapter One - Digital Mapping of Soil Carbon. *Advances in Agronomy*. 118, 1-47. <https://doi.org/10.1016/B978-0-12-405942-9.00001-3>.

²² National Academies of Sciences, Engineering, and Medicine. (2019). *Negative Emissions Technologies and Reliable Sequestration: A Research Agenda*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25259>.

impacts.²³ These negative impacts can be mitigated through increasing soil health. Healthy soil increases water retention and infiltration capacity on agricultural lands during a time of increased rainfall or flooding conditions. It can also improve water quality and provide resilience against times of drought by storing more water.²⁴

III. Relevant Process and Legal Background

1. Background on the Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA is the primary statute under which EPA regulates the distribution, sale, and use of pesticides. FIFRA defines a “pesticide” as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest[.]”²⁵ When a pesticide is sold or distributed, it is generally referred to as a “pesticide product.” FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been “registered” under FIFRA Section 3.²⁶

Overall, “FIFRA establishes an application procedure by which pesticide products are to be registered by EPA” and for a pesticide’s application, “EPA has promulgated regulations which set forth the types and amounts of data required to be submitted in support of an application.”²⁷ Without this data, the pesticide cannot be registered.²⁸ Finally, “the Pesticide Assessment Guidelines then provide acceptable protocols for conducting tests designed to generate the required data.”²⁹

FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide “will perform its intended function without unreasonable adverse effects on the environment,” and that “when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.”³⁰ The statute defines “unreasonable adverse effects on the environment” to include “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”³¹

²³ NRDC. Climate-Ready Soil: How Cover Crops Can Make Farms More Resilient to Extreme Weather Risks. November 2015. Available here: <https://www.nrdc.org/sites/default/files/climate-ready-soil-IB.pdf>.

²⁴ USDA. Natural Resources Conservation Service Idaho. A Hedge Against Drought: Why Healthy Soil is ‘Water in the Bank.’ Available here: <https://www.nrcs.usda.gov/wps/portal/nrcs/detail/id/home/?cid=NRCSEPRD355634>

²⁵ 7 U.S.C. § 136 (u)(1).

²⁶ 7 U.S.C. § 136a(a).

²⁷ *Lucas v. Bio-Lab, Inc.*, 108 F. Supp. 2d 518, 527 (E.D. Va. 2000).

²⁸ *Id.*

²⁹ *Id.*

³⁰ 7 U.S.C. § 136a(c)(5)(C), (D); 40 C.F.R. § 152.112(e).

³¹ 7 U.S.C. § 136(bb).

To determine if a pesticide has unreasonable adverse effects on the environment, the EPA must necessarily identify all the potential risks to the environment. This does not happen under current practice. This petition seeks the implementation of a soil health analysis in order to incorporate risks to soil organisms in EPA's registration decisions.

2. Background on EPA's Ecological Risk Assessment for Pesticides

EPA's 1998 "Guidelines for Ecological Risk Assessment"³² (hereafter "1998 Guidelines") set forth the ecological risk assessment process for reviewing the impacts of pesticides on the environment in general. An ecological risk assessment is the process for evaluating the probability of an environmental impact resulting from exposure to one or more environmental stressors such as chemicals, land change, disease, invasive species and climate change.³³ The 1998 Guidelines set forth an approach that EPA uses to assess the effects of a pesticide on the soil, surface water, ground water, plants and animals.

The 2004 "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs"³⁴ (hereafter "2004 Overview Guidance") sets out the overall structure of the ecological risk assessment that the agency utilizes to assess risk from pesticides under FIFRA. This includes details on the types of studies analyzed, the models the agency uses, and the overall approach taken.

In addition to the 1998 Guidelines and the 2004 Overview Guidance that dictate the general process by which EPA estimates risk to ecological receptors, EPA has amended that process with the "Guidance for Assessing Pesticide Risks to Bees"³⁵ (Hereafter "2014 Bee Guidance") This document provides further refinement for how EPA assesses risk to honey bees from the use of pesticides.

These three guidance documents dictate the current approach EPA uses to analyze risk to all terrestrial invertebrates from pesticides. This petition seeks to amend this process further with

³² EPA. Guidelines for Ecological Risk Assessment. April 1998. (Hereafter "1998 Guidelines"). Available here: https://www.epa.gov/sites/production/files/2014-11/documents/eco_risk_assessment1998.pdf.

³³ EPA. Ecological Risk Assessment. Accessed April 22, 2021. Available here: <https://www.epa.gov/risk/ecological-risk-assessment#self>.

³⁴ EPA. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations. January 23, 2004. (Hereafter "2004 Overview Guidance"). Available here: <https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf>.

³⁵ EPA, PMRA, CDPR. Guidance for Assessing Pesticide Risks to Bees. June 19, 2014. (Hereafter "2014 Bee Guidance"). Available here: https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf.

regulations and guidance that incorporate a risk analysis of soil organisms and the ecosystem services they provide.

3. Overview of 40 C.F.R. 158 and Current Data Requirements for Pesticides

Codified in 40 C.F.R. 158, EPA issued Pesticide Assessment Guidelines which set forth acceptable protocols for conducting tests to develop the required data.³⁶ From these guidelines is the general policy that EPA,

will determine whether the data submitted or cited to fulfill the data requirements specified in [40 C.F.R.158] are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible.³⁷

Regulations finalized on October 26, 2007 outline the agency's data requirements used to make regulatory judgments under FIFRA sections 3, 4, and 5 about the risks and benefits of pesticide products.³⁸ These regulations establish a baseline level of study that must be completed for the agency to analyze ecological effects from pesticide use. The required data for most outdoor uses of a pesticide include: Two avian oral LD₅₀, two avian dietary LC₅₀, two avian reproduction studies, two freshwater fish LC₅₀, one freshwater invertebrate EC₅₀, one honeybee acute contact LD₅₀, one freshwater fish early-life stage, one freshwater invertebrate life cycle, and three estuarine acute LC₅₀/EC₅₀ studies (fish, mollusk and invertebrate).³⁹ Mammalian toxicity studies that are required for human health risk assessment are also incorporated into the ecological risk assessment. If certain toxicity/exposure conditions are met, further study may be required.

EPA's 2014 Bee Guidance⁴⁰ implemented additional data requirements when the potential for *pollinator* exposure is present. In addition to the honeybee acute contact LD₅₀ test requirement, registrants must submit acute and chronic oral toxicity studies for adult and

³⁶ 40 C.F.R. § 158.70; *Lucas v. Bio-Lab, Inc.*, 108 F. Supp. 2d 518, 527 (E.D. Va. 2000).

³⁷ 40 C.F.R. § 158.70.

³⁸ 40 CFR § 158.630

³⁹ 72 FR 60978. Federal Register notice. Pesticides; Data Requirements for Conventional Chemicals. October 26, 2007.

⁴⁰ 2014 Bee Guidance.

larval honeybees if exposure via pollen or nectar is possible.⁴¹ With this guidance, EPA has implemented a tiered process whereby additional study requirements are triggered if certain conditions are met. These studies can include semi-field/tunnel assays and field testing for nectar/pollen contamination.⁴² There are currently no data requirements for toxicity to species other than the European honey bee, which lives in above ground hives, unlike the majority of ground nesting native bee species. Furthermore, soil-applied pesticides that are not systemic are exempt from the new pollinator data requirements.

There are currently no data requirements or analyses done for toxicity to terrestrial or aquatic microorganisms like beneficial bacteria, protozoa or fungi.

IV. Current Surrogacy for Terrestrial Invertebrates in Ecological Risk Assessment is Insufficient to Estimate Harm to Soil Ecosystems

Data requirements are important in that they establish a minimum amount of study for certain taxon that must be met in order to consider registration of a pesticide. They also provide the framework for the quantitative risk assessment process. Pesticide ecological risk assessment in the U.S. quantifies risks to mammals, birds, fish, aquatic invertebrates and invertebrate pollinators. Those five categories constitute the ecological risk assessment to non-target animals and, more importantly, provide for the identification of mitigation measures that can be implemented when risk to environmental receptors is high. Risk to those five broad categories is often estimated by a few test species that are used as “surrogates” for all other species in that category. For instance, risk to all birds, terrestrial-phase reptiles and amphibians is often estimated from toxicity studies done on two to three species of birds. Similarly, risk to all fish and aquatic-phase amphibians is often estimated from toxicity studies done on two species of fish.

The broadest application of surrogacy in the ecological risk assessment for pesticides is with terrestrial invertebrates. In most cases, risk to all terrestrial invertebrates is estimated from toxicity to just a single species: the European honey bee (*Apis mellifera*). The agency reserves the right to analyze data on other species of terrestrial invertebrates if such data happen to exist and are brought to the attention of the agency, however, we have never observed such data used in a quantitative manner that has impacted ecological risk characterization. So, for practical purposes, data on other terrestrial invertebrate species rarely impact the risk analysis and are largely ignored when making risk management decisions.

⁴¹ *Id.* at 19-20.

⁴² EPA. Honeybee Toxicity Testing Frequently Asked Questions – August 16, 2018. Available here: <https://www.epa.gov/sites/production/files/2018-08/documents/pollinator-faq.pdf>.

Coincident with having only a single species used as a surrogate for toxicity calculations, exposure estimates for all terrestrial invertebrates currently only focus on exposure to invertebrate pollinators, using the European honey bee as the primary example. In EPA's ecological risk assessment, the only exposure routes analyzed for terrestrial invertebrates include direct contact with aerial droplets and ingestion of contaminated pollen and nectar. Therefore, the surrogate species used in ecological risk assessment not only dictates the effects characterization for its associated taxon, but also the exposure characterization as well.

An effective surrogate species is not only easy to study, but also provides a suitable representation of the species it is supposed to represent. The European honey bee has the benefit of being conducive to study in a lab and field environment, however this single species is poorly suited to represent all other terrestrial invertebrates in the United States. First, invertebrates comprise roughly 85% of all described animal species globally, with vertebrates comprising about 3% (the remaining 12% are microorganisms).⁴³ This vast difference in species number reflects a comparable difference in species diversity. This indicates that many more terrestrial invertebrates will differ significantly in their seasonal timing of emergence, life span, contact with soil, degree of sociality, chemical sensitivity, and foraging and nesting behavior from their surrogate species than vertebrates. Thus, terrestrial invertebrates are not as suitably represented in the current risk assessment process as vertebrates, and this can lead to a greater potential for harm.

Second, an EPA-hosted workshop on the adequacy of *Apis* bees as effective surrogates for non-*Apis* bees concluded that risk estimation based on data from *Apis* bees is not always protective of non-*Apis* bees like bumble bees.⁴⁴ Considering that bumble bees and honey bees are relatively closely related and share the very rare trait of being eusocial, this indicates that terrestrial invertebrate species that are even more divergent from honey bees (i.e. nearly every soil invertebrate) would likely be even more poorly represented by EPA's current ecological risk assessment approach.

EPA's surrogacy approach for terrestrial invertebrates is also insufficient in light of the agency's current risk characterization of aquatic invertebrates. For all pesticides with an outdoor use pattern, the agency requires toxicity testing on at least one freshwater invertebrate species (often *Daphnia magna*) and at least two estuarine/marine invertebrate species (often one crustacean and

⁴³ Chapman, A.D. 2009. Number of Living Species in Australia and the World 2nd Edition. Australian Biodiversity Information Services, Toowoomba, Australia. Available from <https://www.environment.gov.au/system/files/pages/2ee3f4a1-f130-465b-9c7a-79373680a067/files/nlsaw-2nd-complete.pdf>.

⁴⁴ Gradish, A. E., Van der Steen, J., Scott-Dupree, C. D., Cabrera, A. R., Cutler, G. C., Goulson, D., ... Thompson, H. (2018). Comparison of pesticide exposure in honey bees (Hymenoptera: Apidae) and bumble bees (Hymenoptera: Apidae): Implications for risk assessments. *Environmental Entomology*, 48(1), 12-21. doi:10.1093/ee/nvy168.

one mollusc species).⁴⁵ In 2014, the EPA issued a memorandum to implement aquatic sediment toxicity testing for most outdoor-use pesticides, which includes studies on one or more of the following benthic invertebrate(s): an estuarine/marine amphipod, a freshwater amphipod or a freshwater midge.⁴⁶ Further data are required if the potential for water contamination is significant.⁴⁷ The testing requirement for at least four different aquatic invertebrate species indicates a clear acknowledgment by the EPA that significant differences exist between invertebrate species that reside in different environmental phases – not only in chemical sensitivity, but in exposure potential as well. This is often reflected in the agency’s ecological risk assessment, where freshwater, estuarine/marine and benthic invertebrates are analyzed individually with different effect and exposure estimates. This sometimes results in a similar risk characterization for the different taxa and other times indicates that one or more has a much higher potential for harm. This is important information to obtain and ultimately strengthens the risk assessment.

Terrestrial invertebrates, like aquatic invertebrates, also live in different environmental phases – none of which are more divergent than the subterranean and above-ground environments. Yet, while there is a clear similarity between aquatic and terrestrial invertebrates that live above and below the ground/sediment, they are treated very differently in the risk assessment process. In fact, terrestrial subterranean invertebrate species can diverge as much from above-ground invertebrate species in their risk from chemical harm as do freshwater, benthic and marine invertebrates. Yet, under current ecological risk assessment practice, aquatic invertebrates in different environmental phases are analyzed separately while terrestrial invertebrates in different environmental phases are considered identical.

Here, we are petitioning EPA to strengthen its terrestrial invertebrate risk assessment process for pesticides by including extra data requirements and conducting a separate soil health analysis to characterize risk to soil ecosystems. These proposed requirements would be in addition to the pollinator risk assessment and data requirements the agency already requires.

V. A Soil Health Endpoint Meets EPA’s Criteria for Inclusion in Pesticide Ecological Risk Assessment

This petition seeks to implement a “Soil Health” endpoint in EPA’s ecological risk assessment process for pesticides. Overall, soil health would be inferred through studies in the primary and gray literature in addition to tests on six species/processes that adequately represent the

⁴⁵ 40 CFR § 158.630.

⁴⁶ EPA. Memorandum. Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates. April 10, 2014. Available here: https://www.epa.gov/sites/production/files/2015-08/documents/toxtesting_ecoriskassessmentforbenthicinvertebrates.pdf.

⁴⁷ 40 CFR § 158.630.

ecosystem services provided by agricultural soils. This will allow the agency to quantify and analyze risk to soil ecosystems and effectively mitigate any risk in compliance with federal law.

EPA's 1998 Guidelines⁴⁸ provide the current guidance the agency uses for conducting ecological risk assessment for its duties under federal environmental laws. This guidance document lays out three criteria that should be met in order to define and select an assessment endpoint for inclusion in ecological risk assessment. These three principal criteria are: (1) ecological relevance, (2) susceptibility to known or potential stressors, and (3) relevance to management goals.⁴⁹ The 1998 Guidelines go on to state: "Assessment endpoints that meet all three criteria provide the best foundation for an effective risk assessment."⁵⁰

Below, we outline why a soil health endpoint meets all three criteria for inclusion in any pesticide ecological risk assessment where the potential for soil contamination is present.

1. Ecological Relevance

In its 1998 Guidance, EPA defines ecologically relevant endpoints as helping "...sustain the natural structure, function, and biodiversity of an ecosystem or its components. They may contribute to the food base (e.g., primary production), provide habitat (e.g., for food or reproduction), promote regeneration of critical resources (e.g., decomposition or nutrient cycling), or reflect the structure of the community, ecosystem, or landscape (e.g., species diversity or habitat mosaic)."⁵¹

Along these same lines, the European Food Safety Authority (EFSA) recently convened the Panel on Plant Protection Products and their Residues (PPR) to advise EFSA on the state of the science for analyzing risk to in-soil organisms (Hereafter "EFSA PPR Panel").⁵² As part of its charge, the scientific panel identified seven important ecosystem services that are driven by soil organisms, *specifically in the agricultural landscape*. These include:

- 1) Genetic resources, biodiversity. In-soil organisms are extremely diverse and contribute highly to the biodiversity of agricultural landscapes.

⁴⁸ 1998 Guidelines.

⁴⁹ *Id.* at 30.

⁵⁰ *Id.*

⁵¹ *Id.* at 31.

⁵² EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Ockleford C, Adriaanse P, Berny P, Brock T, Duquesne S, Grilli S, Hernandez-Jerez AF, Bennekou SH, Klein M, Kuhl T, Laskowski R, Machera K, Pelkonen O, Pieper S, Stemmer M, Sundh I, Teodorovic I, Tiktak A, Topping CJ, Wolterink G, Craig P, de Jong F, Manachini B, Sousa P, Swarowsky K, Auteri D, Arena M and Rob S, 2017. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms. EFSA Journal 2017;15(2):4690, 225 pp. doi:10.2903/j.efsa.2017.4690. (Hereafter "EFSA PPR Panel").

- 2) Education and inspiration, aesthetic values and cultural diversity. In-soil organisms support with their activity the formation of typical structures in agricultural landscapes, delivering aesthetic values, cultural heritage and sense of place. The aesthetic value of soils is widely acknowledged.
- 3) Nutrient cycling. The cycling of nutrients in soils is the basis for terrestrial life. Dead organic matter from above and below-ground is degraded by detritivores and finally mineralized by microorganisms. Mineralized nutrients can be then taken up by plants.
- 4) Regulation of pest populations and of disease outbreaks. In-soil organisms are valuable antagonists of soil-borne pests affecting crop-plant species and have the potential to control the outbreaks of plant diseases.
- 5) Soil remediation, natural attenuation. In-soil organisms degrade a variety of compounds in soils and contribute to the natural attenuation of xenobiotic soil pollution, including pesticides and their residues.
- 6) Soil-structure formation, water retention and regulation. In-soil organisms are important drivers of soil-structure formation and maintenance. The activity of soil organisms modulates aggregate formation, alleviates soil compaction and regulates soil water-holding capacity.
- 7) Food provision, food-web support. In-soil organisms are part of the below-ground food web and are the link to above-ground consumers. They are providers of secondary production and support biodiversity at a higher trophic level.⁵³

While the European Union and the United States have different statutory obligations and policies involving pesticide regulation, the question of ecological relevance is – at its heart – a scientific question. Therefore, this scientific resource is valuable for identifying the importance of soil ecosystems and the services they provide.

All seven of these ecosystem services provided by agricultural soils are driven by key soil organisms. Based on the diverse types of organisms and services they provide, the EFSA PPR Panel recommended pesticide toxicity tests on six species or processes to adequately represent these seven important ecosystem services. This is the basis for the proposed changes to 40 C.F.R. 158.630(d). Four of these six tests are currently utilized in pesticide risk assessment in the European Union, and two are under consideration:

- 1) Sublethal effects to the earthworm (*Eisenia fetida* or *Eisenia andrei*)⁵⁴
- 2) Sublethal effects to the springtail (*Folsomia candida* or *Folsomia fimetaria*)⁵⁵

⁵³ *Id.* at 21.

⁵⁴ OECD (Organization for Economic Co-operation and Development), 2004. Earthworm Reproduction Test (*Eisenia fetida*/*Eisenia andrei*) (No. 222). OECD Guidelines for the Testing of Chemicals. OECD, Paris, France.

⁵⁵ OECD (Organization for Economic Co-operation and Development), 2009. Collembolan Reproduction Test in Soil (No. 232). OECD Guidelines for the Testing of Chemicals. OECD, Paris, France.

- 3) Sublethal effects to the mite (*Hypoaspis aculeifer*)⁵⁶
- 4) Effects on nitrogen transformation (readout of soil microbial activity)⁵⁷
- 5) Sublethal effects to an isopod species – currently under consideration
- 6) Effects on mycorrhizal fungi (*Funneliformis mosseae*) – currently under consideration⁵⁸

Aside from the proposed isopod test (#5), all tests have currently approved Organization for Economic Co-operation and Development (OECD) and/or International Organization for Standardization (ISO) guidelines for laboratory analysis. Although some of these species/processes are not the most sensitive to pesticides,^{59,60} and therefore not necessarily conservative surrogates, we feel that the European Union’s framework provides an achievable blueprint for how the EPA can begin to assess risk to soil ecosystems from pesticide contamination. This process could be tiered, such that the outcome of the risk analysis with the first six tests could be further refined in higher-tier field studies (similar to how the EPA conducts its pollinator risk assessment for pesticides).⁶¹

In its guidance on defining ecologically relevant endpoints, EPA states: “Ecologically relevant endpoints may be identified at any level of organization (e.g., individual, population, community, ecosystem, landscape). The consequences of changes in these endpoints may be quantified (e.g., alteration of community structure from the loss of a keystone species) or inferred (e.g., survival of individuals is needed to maintain populations).”⁶²

An overall soil health endpoint in pesticide ecological risk assessment can be inferred from the proposed six ecologically relevant endpoints on soil organisms. Not only is a soil health endpoint important and relevant to soil ecosystems in the agricultural landscape, but it can help prevent cascading effects to other organisms the agency already analyzes as part of its pesticide risk assessment process. The interrelationship between soil ecosystems and aquatic and terrestrial organisms is well-characterized. For example, nutrient cycling is essential for plant growth, soil organisms provide food for many terrestrial vertebrates like mammals and birds, and soil structure is necessary for water retention and preventing runoff of sediment and contaminants

⁵⁶ OECD (Organization for Economic Co-operation and Development), 2008. Predatory mite (*Hypoaspis* (*Geolaelaps*) *aculeifer*) reproduction test in soil (No. 226). OECD Guidelines for the Testing of Chemicals. OECD, Paris, France.

⁵⁷ OECD (Organization for Economic Co-operation and Development), 2000. Soil Microorganisms: Nitrogen Transformation Test (No. 216). OECD Guidelines for the Testing of Chemicals. OECD, Paris, France.

⁵⁸ ISO (International Organisation for Standardization), 2009. Soil quality— effects of pollutants on mycorrhizal fungi—spore germination test (ISO/TS 10832).

⁵⁹ Frampton, G. K., Jänsch, S., Scott-Fordsmand, J. J., Römcke, J., & Van den Brink, P. J. (2006). Effects of pesticides on soil invertebrates in laboratory studies: A review and analysis using species sensitivity distributions. *Environmental Toxicology and Chemistry*, 25(9), 2480. doi:10.1897/05-438r.1.

⁶⁰ Daam, M. A., Leitão, S., Cerejeira, M. J., & Paulo Sousa, J. (2011). Comparing the sensitivity of soil invertebrates to pesticides with that of *Eisenia fetida*. *Chemosphere*, 85(6), 1040-1047. doi:10.1016/j.chemosphere.2011.07.032.

⁶¹ 2014 Bee Guidance.

⁶² 1998 Guidance. Pages 30-31.

into nearby waterways. Therefore, a soil health endpoint will enable the EPA to quantify risk to these vital soil ecosystems and ensure that other environmental receptors that the EPA has already identified as ecologically relevant, such as mammals, birds, fish and plants, aren't indirectly affected via negative effects to soil organisms/processes.

2. Susceptibility to Known or Potential Stressors

In its 1998 Guidance, EPA uses the following passage as a guide to determine susceptibility: “Ecological resources are considered susceptible when they are sensitive to a stressor to which they are, or may be, exposed.”⁶³

Due to the widespread use of pesticides in the United States, there is considerable evidence that soil organisms are regularly exposed to pesticides in agricultural and non-agricultural environments. There is also considerable evidence that pesticides of all types can harm soil organisms. Susceptibility will vary between different species, pesticides and use scenarios. However, when the potential for soil exposure exists, there is a clear hazard to all species of soil organisms to all types of pesticides. Presence of pesticides in soil has also been negatively correlated with soil health endpoints.⁶⁴ Therefore, this petition seeks inclusion of a “Soil Health” endpoint in the ecological risk assessment for any pesticide that is reasonably expected to come into contact with soil.

Below, we discuss evidence that soil health should be considered susceptible to all types of pesticides in the outdoor environment based on potential exposure and sensitivity.

a. Exposure

In determining potential exposures, EPA will often identify whether an exposure pathway is complete or incomplete. A complete exposure pathway is “one in which the stressor can be traced or expected to travel from the source to a receptor that can be affected by that stressor.”⁶⁵ Pesticides can be applied in many different manners that offer a complete exposure pathway to the soil environment. Many are applied directly to the soil, such as fumigants, granular products and soil drenches. Others can be applied to the soil via a carrier, like irrigation water or crop

⁶³ *Id.* at 32.

⁶⁴ Riedo, J., Wettstein, F. E., Rösch, A., Herzog, C., Banerjee, S., Büchi, L., ... Van der Heijden, M. G. (2021). Widespread occurrence of pesticides in organically managed agricultural soils—the ghost of a conventional agricultural past? *Environmental Science & Technology*. doi:10.1021/acs.est.0c06405.

⁶⁵ EPA. EPA EcoBox Tools by Exposure Pathways - Exposure Pathways In ERA. Accessed April 22, 2021. Available here: <https://www.epa.gov/ecobox/epa-ecobox-tools-exposure-pathways-exposure-pathways-era>.

seeds that are treated with pesticides.^{66,67} Many pesticides that are sprayed into the atmosphere will eventually deposit onto the soil due to gravitational forces.⁶⁸ Pesticides that initially deposit onto plants or are taken up by plants may eventually reach the soil environment following rain, irrigation or death and decay of the plant material.⁶⁹

Pesticide soil contamination has been identified in many agricultural settings, and pesticides applied to the soil can be taken up directly or indirectly by soil organisms.^{70,71,72,73,74} EPA recognizes that soil is one medium that can potentiate pesticide exposure to humans and environmental receptors⁷⁵ and estimates that for agricultural applications, *50-100% of the applied pesticide ends up in the soil.*⁷⁶

The already high burden that soil ecosystems bear from pesticide exposure has been increasing and will likely continue to do so in the future. Pesticides applied outdoors will eventually make their way into the air, water or soil. Often, EPA's mitigations of pesticide harm come in the form of reductions in pesticide levels in the atmosphere or water. This includes implementation of drift reduction measures like increasing spray droplet size, adding anti-drift adjuvants and

⁶⁶ Hitaj, C., Smith, D. J., Code, A., Wechsler, S., Esker, P. D., & Douglas, M. R. (2020). Sowing uncertainty: What we do and don't know about the planting of pesticide-treated seed. *BioScience*, 70(5), 390-403. doi:10.1093/biosci/biaa019.

⁶⁷ Ghidui, G., Kuhar, T., Palumbo, J., & Schuster, D. (2012). Drip Chemigation of insecticides as a pest management tool in vegetable production. *Journal of Integrated Pest Management*, 3(3), E1-E5. doi:10.1603/ipm10022.

⁶⁸ Sanchez-Bayo, F. Impacts of Agricultural Pesticides on Terrestrial Ecosystems. Chapter 4. Ecological Impacts of Toxic Chemicals, 2011, 63-87. doi: 10.2174/97816080512121110101.

⁶⁹ Doublet, J., Mamy, L., & Barriuso, E. (2009). Delayed degradation in soil of foliar herbicides glyphosate and sulcotrione previously absorbed by plants: Consequences on herbicide fate and risk assessment. *Chemosphere*, 77(4), 582-589. doi:10.1016/j.chemosphere.2009.06.044.

⁷⁰ Silva, V., Mol, H. G., Zomer, P., Tienstra, M., Ritsema, C. J., & Geissen, V. (2019). Pesticide residues in European agricultural soils – A hidden reality unfolded. *Science of The Total Environment*, 653, 1532-1545. doi:10.1016/j.scitotenv.2018.10.441.

⁷¹ Carey, A.E. (1979). Monitoring pesticides in agricultural and urban soils of the United States. *Pestic Monit J*, 1, 23-27.

⁷² Humann-Guillemot, S., Binkowski, L. J., Jenni, L., Hilke, G., Glauser, G., & Helfenstein, F. (2019). A nationwide survey of neonicotinoid insecticides in agricultural land with implications for agri-environment schemes. *Journal of Applied Ecology*, 56(7), 1502-1514. doi:10.1111/1365-2664.13392.

⁷³ Schaafsma, A., Limay-Rios, V., Baute, T., Smith, J., & Xue, Y. (2015). Neonicotinoid insecticide residues in surface water and soil associated with commercial maize (Corn) fields in southwestern Ontario. *PLOS ONE*, 10(2), e0118139. doi:10.1371/journal.pone.0118139.

⁷⁴ Douglas, M. R., Rohr, J. R., & Tooker, J. F. (2014). Editor's CHOICE: Neonicotinoid insecticide travels through a soil food chain, disrupting biological control of non-target pests and decreasing soya bean yield. *Journal of Applied Ecology*, 52(1), 250-260. doi:10.1111/1365-2664.12372.

⁷⁵ EPA. Expobox. Exposure Assessment Tools by Chemical Classes – Pesticides. Accessed April 22, 2021. Available here: <https://www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-pesticides>.

⁷⁶ EPA. National Management Measures to Control Nonpoint Source Pollution from Agriculture. EPA 841-B-03-004. Chapter 4B: Pesticide Management. Figure 4b-4. July 2003. Available here: <https://www.epa.gov/sites/production/files/2015-10/documents/chap4b.pdf>.

lowering sprayer height,⁷⁷ or runoff reduction measures like no-spray buffers near waterways and restrictions on application before rainfall. While these mitigations can be effective in reducing atmospheric and water presence of pesticides, most of them work by increasing soil deposition.

Together with increasing soil deposition via drift and runoff mitigations, soil application of pesticides is also becoming more common. Pesticide seed treatment has increased dramatically in the last 20 years,⁷⁸ and many new active ingredients or new pesticide uses that have been approved or are under consideration by the EPA are predominantly soil applied.^{79,80,81,82} Soil applied pesticides are often touted as “safer” than foliar applied pesticides⁸³ and may be utilized more frequently due to that perception. But qualifying these applications as “safer” does not account for the risks to soils and the organisms that depend on them because pesticide regulators do not conduct such an analysis in the U.S.

Therefore, all outdoor uses of pesticides are reasonably expected to come into contact with the soil environment to some extent. With mitigations being increasingly implemented for drift and runoff that are expected to increase soil deposition and recent shifts toward use of soil-applied pesticides, this exposure pathway is likely to become of even greater concern in the future.

b. Effects

Pesticide is an umbrella term inclusive of any agent that targets a pest. This includes insecticides, herbicides, fungicides, bactericides, avicides, among others. Each pesticide type encompasses multiple classes of chemicals or agents that function differently at a molecular or biological level resulting in varying harm to different non-target taxa.

Assigning effects to such a large and diverse group of agents is difficult, particularly to the diverse group of organisms that reside and develop in the soil environment. Numerous studies

⁷⁷ EPA. About the Drift Reduction Technology Program. Accessed April 22, 2021. Available here: <https://www.epa.gov/reducing-pesticide-drift/about-drift-reduction-technology-program>.

⁷⁸ Hitaj, C., Smith, D. J., Code, A., Wechsler, S., Esker, P. D., & Douglas, M. R. (2020). Sowing uncertainty: What we do and don't know about the planting of pesticide-treated seed. *BioScience*, 70(5), 390-403. doi:10.1093/biosci/biaa019.

⁷⁹ EPA (2020). Final Registration Decision for the New Active Ingredient Inpyrfluxam. Available at: <https://www.regulations.gov/document/EPA-HQ-OPP-2018-0038-0040>.

⁸⁰ EPA (2020). Proposed Registration Decision for the New Active Ingredient Tetraniliprole. Available at: <https://www.regulations.gov/document/EPA-HQ-OPP-2017-0233-0024>.

⁸¹ EPA (2020). Proposed Registration Decision for the New Active Ingredient Broflanilide. Available at: <https://www.regulations.gov/document/EPA-HQ-OPP-2018-0053-0027>.

⁸² EPA (2021). Registration Decision for the Uses on Oranges and Grapefruit in Florida, Aldicarb. Available at: <https://www.regulations.gov/document/EPA-HQ-OPP-2020-0600-0023>.

⁸³ Ghidui, G., Kuhar, T., Palumbo, J., & Schuster, D. (2012). Drip Chemigation of insecticides as a pest management tool in vegetable production. *Journal of Integrated Pest Management*, 3(3), E1-E5. doi:10.1603/ipm10022.

and review papers have identified harms from particular classes of pesticides to particular species of soil organisms in various settings. Instead of compiling and citing the available literature for this petition, we will focus on two resources that have attempted to compile the exhaustive amount of literature on this topic in order to analyze how all pesticide types affect the diversity of soil organisms in the field and laboratory setting. These reviews are well-cited and are great resources if further detail is required.

Puglisi, 2012 - Microorganisms⁸⁴

This study reviewed the effects of all pesticide types on terrestrial and aquatic microbial organisms in the published literature. Since this petition only focuses on the terrestrial soil environment, all further discussion will be restricted to only the terrestrial results of the paper. In the 234 studies identified in the literature of the effects of pesticides to terrestrial microorganisms, the author extracted 3,406 “case studies” which were data points related to the effect of a certain pesticide on a certain microbial endpoint at a certain dose.⁸⁵ The 254 individual endpoints that were analyzed in these studies were put into one of three categories: biomass, activity and structure.⁸⁶ This analysis incorporated data on 225 active ingredients, representing a wide variety of pesticide types (74 fungicides, 80 herbicides, 60 insecticides and 11 “other” types).⁸⁷

The author found that terrestrial microbial activity was significantly impacted in 55%, 61% and 53% of case studies for fungicides, herbicides and insecticides, respectively.⁸⁸ Microbial biomass was significantly impacted in 75%, 45% and 62% of case studies for fungicides, herbicides and insecticides, respectively.⁸⁹ And microbial structure was significantly impacted in 87%, 76% and 95% of case studies for fungicides, herbicides and insecticides, respectively.⁹⁰ Significant impacts in this study included impacts that were judged to be positive or negative. The author did not provide exact percentages of how many of the aforementioned effects were categorized as positive or negative, but from the Figures in the paper it is clear that negative effects made up the majority of effects for most pesticide types and endpoints. We also caution against viewing any effects as “positive,” because a positive effect on one species or taxa will likely come at the expense of other species or taxa in the ecosystem. For example, increased microbial activity could result in resource depletion for other species or could be an indirect effect of predators being negatively impacted by the pesticide. Therefore, we believe that *any*

⁸⁴ Puglisi, E. (2012). Response of microbial organisms (aquatic and terrestrial) to pesticides. *EFSA Support. Publ.* 9, 359E. doi:10.2903/sp.efsa.2012.EN-359. (Hereafter “Puglisi, 2012”)

⁸⁵ Puglisi, 2012. Pg 73.

⁸⁶ Puglisi, 2012. Pgs 2, 73.

⁸⁷ Puglisi, 2012. Pg 73.

⁸⁸ Puglisi, 2012. Pgs 39-43.

⁸⁹ Puglisi, 2012. Pgs 43-46.

⁹⁰ Puglisi, 2012. Pgs 47-51.

effect of pesticides be categorized as a negative effect to ecosystem homeostasis and functioning.

In 43% of the case studies analyzed, the author was able to extract information on how the pesticide dosage related to field doses that may be encountered in the environment.⁹¹ Negative impacts were seen at “field-relevant” doses for all pesticide types, albeit at lower percentages than when accounting for all doses.⁹² The paper concludes that pesticides can impact terrestrial microbial communities and recommends implementing pesticide risk assessment for non-target microbes and including multiple parameters to account for the number of endpoints that can be affected.⁹³ This indicates that a wide variety of non-target effects can occur to terrestrial microbes following exposure to all pesticide types.

Gunstone et al., 2021 – Invertebrates⁹⁴

This study reviewed the effects of all pesticide types on terrestrial soil invertebrates. Terrestrial soil invertebrates were defined as non-target invertebrates that have egg, larval, or immature development in the soil. This included Oligochaeta (earthworms), Enchytraeidae (potworms), Nematoda (roundworms), Tardigrada (water bears), Acari (mites), Myriapoda (centipedes and millipedes), Isopoda (woodlice), Collembola (springtails), Protura (coneheads), Isoptera (termites), Coleoptera (beetles), Formicidae (ants), *Bombus* spp. (bumble bees), other ground-nesting bees, and parasitic wasps.⁹⁵

The authors identified 394 studies that fit their inclusion criteria. From these studies, they extracted 2,842 unique “tested parameters” (similar to the “case studies” in the Puglisi study) that measured a specific endpoint following exposure of a specific organism to a specific pesticide.⁹⁶

The diverse array of endpoints in the identified studies were classified into nine broad categories: Mortality, Abundance, Biomass, Behavior, Reproduction, Biochemical Biomarkers, Growth, Richness and Diversity, and Structural Changes.⁹⁷ The identified studies in the literature analyzed how 284 different pesticide active ingredients or unique mixtures of active ingredients (110 insecticides, 68 herbicides, 55 fungicides, two

⁹¹ Puglisi, 2012. Pgs 38-39.

⁹² Puglisi, 2012. Figures 13, 15, 17, 19, 21, 23, 25, 27, 29.

⁹³ Puglisi, 2012. Pgs 73-75.

⁹⁴ Gunstone, T., Cornelisse, T., Klein, K., Dubey, A., & Donley, N. (2021). Pesticides and soil invertebrates: A hazard assessment. *Frontiers in Environmental Science*, 9. doi:10.3389/fenvs.2021.643847. (Hereafter “Gunstone et al., 2021”)

⁹⁵ Gunstone et al., 2021. Pg 4.

⁹⁶ Gunstone et al., 2021. Pg 5.

⁹⁷ Gunstone et al., 2021. Pg 4.

bactericides, and 49 pesticide mixtures) affect 275 unique species, taxa or combined taxa of soil organisms.⁹⁸

The authors found that negative effects to species dominated the analyzed tested parameters, with 70.5% of the tested parameters showing negative effects, 1.4% showing positive effects and 28.1% showing no significant effects from pesticide exposure.⁹⁹ Negative effects were identified for the majority of tested parameters for all pesticide types analyzed: 74.9% for insecticides, 63.2% for herbicides, 71.4% for fungicides, 57.7% for bactericides, and 56.4% for pesticide mixtures.¹⁰⁰

Categorized by endpoint, negative effects were identified for the majority of tested parameters for six of the nine analyzed endpoints: Mortality, Behavior, Reproduction, Biochemical Biomarkers, Growth, and Structural Changes. The remaining three endpoints – Biomass, Abundance, and Richness and Diversity – had 40.0%, 45.2%, and 47.1% of tested parameters showing negative effects, respectively.¹⁰¹ Categorized by taxa, negative effects were identified for the majority of tested parameters for every soil taxa analyzed except for Protura (which was only represented by one tested parameter).¹⁰²

The authors did not incorporate data on pesticide dose, and therefore do not come to any conclusions regarding individual pesticide risk. However, they note that nearly 40% of tested parameters come from field studies, which often use field-relevant doses.¹⁰³

These two studies indicate that pesticides of all types pose a hazard to an extensive variety of soil microorganisms and invertebrates. This hazard, identified from the available literature, establishes that soil organisms are susceptible to pesticide stress. Together with the known – and increasing – exposure potential to the soil environment, the next necessary step is for a risk assessment to be conducted for any pesticide that will result in soil contamination.

3. Relevance to Management Goals

Risk assessment is the way the EPA identifies the potential for harm from its regulatory decisions. In its 1998 Guidance, EPA states: “Ultimately, the effectiveness of a risk assessment depends on whether it is used and improves the quality of management decisions.”¹⁰⁴ In

⁹⁸ Gunstone et al., 2021.

⁹⁹ Gunstone et al., 2021. Pg 5.

¹⁰⁰ Gunstone et al., 2021. Pg 5.

¹⁰¹ Gunstone et al., 2021. Table 2.

¹⁰² Gunstone et al., 2021. Table 1.

¹⁰³ Gunstone et al., 2021. Supplemental Tables 5,6.

¹⁰⁴ 1998 Guidelines at 34.

identifying management decisions, the EPA looks to “...find ecological values that meet the necessary scientific rigor as assessment endpoints that are also recognized as valuable by risk managers and the public.”¹⁰⁵

A “Soil Health” endpoint not only meets the agency’s requirements for scientific rigor and public value but is also necessary for the EPA to comply with its statutory requirements under FIFRA. FIFRA authorizes EPA to register a pesticide only upon determining that the pesticide “will perform its intended function without unreasonable adverse effects on the environment,” and that “when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.”¹⁰⁶ The statute defines “unreasonable adverse effects on the environment” to include “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”¹⁰⁷

To determine if a pesticide has unreasonable adverse effects on the environment, the EPA must necessarily identify the potential risks to the environment. This does not happen under current practice. EPA does not estimate or analyze exposure to soil organisms in pesticide risk assessment. Toxicity to soil microbes is simply not analyzed and toxicity to soil invertebrates is assumed to be identical to *Apis mellifera*, an invertebrate that spends none of its life cycle in the soil.

As detailed above in the sub-section “Ecological Relevance,” seven important ecosystem services have been identified that are driven by soil organisms in the agricultural landscape.¹⁰⁸ These include:

- 1) Genetic resources, biodiversity
- 2) Education and inspiration, aesthetic values and cultural diversity
- 3) Nutrient cycling
- 4) Regulation of pest populations and of disease outbreaks
- 5) Soil remediation, natural attenuation
- 6) Soil-structure formation, water retention and regulation
- 7) Food provision, food-web support

In a 1997 interagency discussion document designed to focus EPA efforts on environmental protection, an EPA working group proposed a list of eight ecological concerns that should be prioritized for consideration in the agency’s activities (hereafter “1997 Discussion

¹⁰⁵ *Id.*

¹⁰⁶ 7 U.S.C. § 136a(c)(5)(C), (D); 40 C.F.R. § 152.112(e).

¹⁰⁷ 7 U.S.C. § 136(bb).

¹⁰⁸ EFSA PPR Panel. Page 21.

Document”).¹⁰⁹ One of these ecological concerns – the only one rated as having “very high” ecological significance – is ecosystem functions and services.¹¹⁰ Many of the above ecosystem services provided by agricultural soils overlap with specific ecosystem functions identified in the 1997 Discussion Document (specifically, nutrient cycling, flood control, generation and maintenance of soils, pest and disease control, and provision of biodiversity).

Not only has the agency already acknowledged the importance of soil organisms and the ecosystem services they provide as a significant ecological concern, but the ability of soil organisms to provide these essential services is in decline.^{111,112,113} Many species, like ground beetles, ground-nesting bees and other terrestrial insects that spend some part of their life cycle in the soil, have been precipitously declining in recent decades, and agricultural intensification and pollution are major driving factors.^{114,115,116,117,118,119,120} Worldwide, overuse of chemical controls like pesticides has been identified as the most impactful driver of soil biodiversity loss in the last decade.¹²¹

Therefore, soil organism-mediated ecosystem services are directly relevant to EPA’s management goals. This relevancy is even more pronounced now that these ecosystem services, and the organisms that perform them, are deteriorating.

¹⁰⁹ EPA. Priorities for Ecological Protection: An Initial List and Discussion Document for EPA. January 1997. (hereafter “1997 Discussion Document”). Available here:

<https://cfpub.epa.gov/ncea/risk/era/recordisplay.cfm?deid=12381>.

¹¹⁰ *Id.* at 19-20.

¹¹¹ Veresoglou, S. D., Halley, J. M., and Rillig, M. C. (2015). Extinction risk of soil biota. *Nat. Commun.* 6. doi:10.1038/ncomms9862.

¹¹² Singh, J., Schädler, M., Demetrio, W., Brown, G. G., and Eisenhauer, N. (2019). Climate change effects on earthworms - a review. *SOIL Org.* 91, 114-138-114–138. doi:10.25674/so91iss3pp114.

¹¹³ Díaz, S., Fargione, J., Iii, F. S. C., and Tilman, D. (2006). Biodiversity Loss Threatens Human Well-Being. *PLOS Biol.* 4, e277. doi:10.1371/journal.pbio.0040277.

¹¹⁴ Forister, M. L., Pelton, E. M., and Black, S. H. (2019). Declines in insect abundance and diversity: We know enough to act now. *Conserv. Sci. Pract.* 1, e80. doi:10.1111/csp2.80.

¹¹⁵ Sánchez-Bayo, F., and Wyckhuys, K. A. G. (2019). Worldwide decline of the entomofauna: A review of its drivers. *Biol. Conserv.* 232, 8–27. doi:10.1016/j.biocon.2019.01.020.

¹¹⁶ van Klink, R., Bowler, D. E., Gongalsky, K. B., Swengel, A. B., Gentile, A., and Chase, J. M. (2020). Meta-analysis reveals declines in terrestrial but increases in freshwater insect abundances. *Science* 368, 417–420. doi:10.1126/science.aax9931.

¹¹⁷ Sullivan, G. T., and Ozman-Sullivan, S. K. Alarming evidence of widespread mite extinctions in the shadows of plant, insect and vertebrate extinctions. *Austral Ecol.* n/a. doi: <https://doi.org/10.1111/aec.12932>.

¹¹⁸ Hallmann, C. A., Sorg, M., Jongejans, E., Siepel, H., Hofland, N., Schwan, H., et al. (2017). More than 75 percent decline over 27 years in total flying insect biomass in protected areas. *PLOS ONE* 12, e0185809. doi:10.1371/journal.pone.0185809.

¹¹⁹ Seibold, S., Gossner, M. M., Simons, N. K., Blüthgen, N., Müller, J., Ambarlı, D., et al. (2019). Arthropod decline in grasslands and forests is associated with landscape-level drivers. *Nature* 574, 671–674. doi:10.1038/s41586-019-1684-3.

¹²⁰ Milic'ic, M., Popov, S., Branco, V. V., and Cardoso, P. (2020). Insect threats and conservation through the lens of global experts. *bioRxiv* [Preprint]. doi: 10.1101/2020.08.28.271494.

¹²¹ United Nations Food and Agriculture Organization. (2020). State of knowledge of soil biodiversity - Status, challenges and potentialities: Report 2020. Rome, Italy: FAO doi:10.4060/cb1928en. Pages 313-314.

VI. Pesticide Risk Management Decisions are Impaired by Lack of a Soil Health Endpoint

There are multiple ways that failure to account for impacts to soil health can impair risk management decisions and, in some cases, work against those decisions.

1. Current System Does Not Protect Soil Organisms

EPA uses the European honey bee to estimate toxicity to all terrestrial invertebrates. Even if this were sufficient to estimate exposure and toxicity to soil organisms (which it is not, as detailed above), there is still the issue of how unacceptable risk is actually mitigated on the ground. If EPA finds unacceptable risk in its ecological risk assessment to the honey bee (which is *supposed* to represent all terrestrial invertebrates), then the agency often requires mitigation measures that are designed solely for pollinators.^{122,123,124} This includes mitigations like spray restrictions during flower bloom, increasing droplet size to reduce drift, switch to soil application, or label language identifying a pollinator hazard. While some of these mitigations may have marginal benefits to pollinators, most will have little impact on soil organism exposure to a pesticide. Others are designed to increase soil deposition to an area and, therefore, may exacerbate harmful exposures to subterranean species while reducing it for above-ground species. The effectiveness of mitigation measures must be analyzed with a lens that accounts for all human and ecological receptors or the agency could just be trading one unacceptable harm for another.

Therefore, it is imperative to have a soil health endpoint in risk assessment, not only to adequately estimate risk to the soil ecosystem, but to ensure that soil organisms are fully accounted for when designing mitigations or deciding whether to cancel certain pesticide uses.

2. Current Lack of Soil Health Endpoint Cuts Against Current Management Goals

Due to the widespread importance of soil ecosystems, any resulting harm from pesticides can cascade to other organisms and ecosystems and have devastating effects. For example, EPA can implement mitigation measures to protect fish from pesticide runoff, but if a pesticide is killing burrowing and tunnelling invertebrates and thereby reducing water retention, then the resulting

¹²² EPA (2017). U.S. Environmental Protection Agency's Policy to Mitigate the Acute Risk to Bees from Pesticide Products. Available here: <https://www.regulations.gov/document/EPA-HQ-OPP-2014-0818-0477>.

¹²³ EPA (2019). Decision Memorandum Supporting the Registration Decision for New Uses of the Active Ingredient Sulfoxaflor on Alfalfa, Cacao, Citrus, Corn, Cotton, Cucurbits, Grains, Pineapple, Sorghum, Soybeans, Strawberries and Tree Plantations and Amendments to the Labels. Available here: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0889-0570>.

¹²⁴ EPA (2020). Permethrin: Proposed Interim Registration Review Decision Case Number 2510. Available here: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0039-0129>.

increase in sediment runoff could result in even greater harms to fish. The same goes for terrestrial vertebrates – mitigation measures reducing direct exposure to birds may still result in unacceptable harms due to loss of soil insects that many birds rely on for food.

These types of secondary effects are extremely important because they can harm organisms that EPA *already acknowledges* to be worthy of protection from pesticides. This runs counter to current management goals.

In EPA’s seminal report *The Edgewater Consensus on an EPA Strategy for Ecosystem Protection*,¹²⁵ the agency defines ecological integrity as “the interaction of the physical, chemical, and biological elements of an ecosystem in a manner that ensures the long-term health and sustainability of the ecosystem.” The importance of considering ecological integrity in any environmental assessment is outlined in EPA’s 1997 Discussion Document: “There is not much point in protecting, say, a particular animal without also protecting its food supply, shelter, and the area in which it searches for a mate: An animal deprived of food will starve, and one deprived of shelter will succumb to the elements or predation.”¹²⁶

Protecting soil organisms not only protects them and other animals that rely on them but is also necessary to ensure that pesticides are metabolizing or degrading in accordance with EPA’s own estimates. Microbial degradation is a major pathway by which pesticides break down into smaller components. Different pesticides will degrade at different rates, but every estimate that EPA makes regarding the half-life of a pesticide assumes that all soils essentially contain fully functional degradation pathways. This may not be the case if the ecosystem is damaged.

Not only is soil health worthy of protection in its own right, but its protection is essential to achieving existing management goals the agency has had in place for decades.

VII. Incorporating a Soil Health Endpoint in Risk Assessment is Feasible and Common Practice Abroad

The requested experimentation and analysis will not impose an undue burden on pesticide registrants, and the benefits obtained from this new analysis will significantly outweigh the costs of implementing it.

There are two reasons why the U.S. should harmonize with the scientific study requirements that are in place or currently being considered by the EU:

¹²⁵ EPA. Toward a place-driven approach: The Edgewater consensus on an EPA strategy for ecosystem protection. Ecosystem Protection Workgroup. March 15, 1994. Washington, DC.

¹²⁶ 1997 Discussion Document. Page 13.

- 1) An enormous amount of scientific assessment went into identifying and implementing these requirements in the EU by a highly regarded regulatory agency. These identified endpoints were based on the same ecological relevance parameters EPA has identified in past guidance documents. And many of these study requirements have been in place for decades, making EFSA a great resource to discuss implementation logistics.
- 2) Since most of these requirements have been in place for a long time, registrants for any pesticide that is registered in both the U.S. and the EU have already completed these studies. A recent comparison of pesticides that are registered in the U.S. and the EU found that 219 out of 374 agricultural pesticides approved in the U.S. were also registered in the EU.¹²⁷ Therefore, harmonizing with the EU's requirements will result in the least amount of regulatory burden and will be the quickest to implement.

A soil health analysis is: 1) feasible, as demonstrated by its inclusion in pesticide risk assessment in Europe for multiple decades, and 2) harmonization with the EU's requirements will result in no additional study requirements for registrants for the majority of pesticides registered in the U.S. For those pesticides that are not registered in the EU and which may not have the required studies available, most are almost finished with registration review for this cycle. That means registrants will have at least 10 years from now to plan for the needed studies before data call-in. Furthermore, many new active ingredients proposed for registration in the U.S. will also likely undergo similar regulatory approval in the EU, making these study requirements something that registrants would already have to comply with anyway.

We also note that the requested study requirements are relatively cheap and quick compared to other animal experiments and don't have the same animal welfare concerns associated with them. Therefore, these new study requirements should not result in considerable delays, costs or run counter to the agency's stated goals of reducing testing of higher-order animals.

The biggest burden would be on the EPA to develop new models, new approaches to manage risk to soil organisms and new protocols to ensure that studies from the published literature are incorporated into its analysis and not arbitrarily ignored. EFSA will be a valuable resource in this regard and can significantly aid the EPA in achieving this goal. It is imperative that the agency begin this process immediately, as to ensure it is finalized and implemented by the next round of registration reviews.

¹²⁷ Donley, N. (2019). The USA lags behind other agricultural nations in banning harmful pesticides. *Environmental Health*, 18(1). doi:10.1186/s12940-019-0488-0.

VIII. Action Requested

The petitioners request the following action:

1. Amend Title 40, Code of Federal Regulations to require a soil health analysis and incorporate additional data requirements

a. 40 C.F.R. 152.112

Amend 40 C.F.R. 152.112 to add the following highlighted paragraph:

40 CFR § 152.112 - Approval of registration under FIFRA sec. 3(c)(5).

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

- (a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;
- (b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);
- (c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;
- (d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.
- (e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;
- (f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

(i) In accordance with paragraph (e) of this section, the Agency must account for the harms to soil organisms and the ecosystem services they provide.

b. 40 C.F.R. 158.630(d)

Amend 40 C.F.R. 158.630(d) by inserting the yellow highlighted language into the following table:

(d) *Table.* The following table shows the data requirements for nontarget terrestrial and aquatic organism

Guideline Number	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Forestry	Residential Outdoor	Greenhouse	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
850.2400	Wild mammal toxicity	CR	CR	CR	CR	NR	NR	TGAI	5
850.2300	Avian reproduction	R	R	R	R	NR	NR	TGAI	1, 4
850.2500	Simulated or actual field testing	CR	CR	CR	CR	NR	NR	TEP	6, 7
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 8, 9, 26
850.1010	Acute toxicity freshwater invertebrates	R	R	R	R	CR	CR	TGAI, TEP	1, 2, 9, 10, 26

850.1025 850.1035 850.1045 850.1055 850.1075	Acute toxicity estuarine and marine organisms	R	R	R	R	NR	NR	TGAI, TEP	1, 9, 11, 12, 26
850.1300	Aquatic invertebrate life cycle (freshwater)	R	R	R	R	NR	NR	TGAI	1, 10, 12
850.1350	Aquatic invertebrate life cycle (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 14, 15
850.1400	Fish early-life stage (freshwater)	R	R	R	R	NR	NR	TGAI	1, 12, 13
850.1400	Fish early-life stage (saltwater)	CR	CR	CR	CR	NR	NR	TGAI	12, 15, 16
850.1500	Fish life cycle	CR	CR	CR	CR	NR	NR	TGAI	17, 18
850.1710 850.1730 850.1850	Aquatic organisms bioavailability, biomagnification, toxicity	CR	CR	CR	CR	NR	NR	TGAI, PAI, degradate	19
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	NR	NR	TEP	7, 20
Sediment Testing									
850.1735	Whole sediment: acute freshwater invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21

850.1740	Whole sediment: acute marine invertebrates	CR	CR	CR	CR	NR	NR	TGAI	21, 23
	Whole sediment: chronic invertebrates freshwater and marine	CR	CR	CR	CR	NR	NR	TGAI	22, 23
Soil Health Testing									
	<u>Sublethal effects to the earthworm</u>	R	R	R	R	NR	NR	TEP	
	<u>Sublethal effects to the springtail</u>	R	R	R	R	NR	NR	TEP	
	<u>Sublethal effects to the mite</u>	R	R	R	R	NR	NR	TEP	
	<u>Effects on nitrogen transformation</u>	R	R	R	R	NR	NR	TEP	
	<u>Sublethal effects to an isopod species</u>	R	R	R	R	NR	NR	TEP	
	<u>Effects on mycorrhizal fungi</u>	R	R	R	R	NR	NR	TEP	
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	CR	R	R	NR	NR	TGAI	1
850.3030	Honey bee toxicity of residues on foliage	CR	CR	CR	CR	NR	NR	TEP	24

§50.3040	Field testing for pollinators	CR	CR	CR	CR	NR	NR	TEP	25
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2. Create a Soil Health Guidance Document

This petition proposes the creation of a Soil Health Guidance document similar to previous guidelines the agency has developed, for example the EPA’s 2014 Bee Guidance.¹²⁸ These guidelines will further direct the agency in the practices required to incorporate the analysis and data required in the above amended regulations (along with the broader scientific literature) into the ecological risk assessment process. This Guidance document should provide guidance to risk assessors for evaluating the potential risk of pesticides to soil organisms. This includes information on the phases of the assessment (i.e., problem formulation, analysis, and risk characterization), specifics on a tiered approach by which additional information can be requested from the registrant, and the modelling approach that is to be used in the assessment. Importantly, this guidance document should outline an approach that effectively incorporates studies in the published literature and does not arbitrarily discount those studies. While data requirements are in place to ensure that a minimum amount of study is available to the EPA, those required studies are rarely of higher scientific quality than studies in the primary and gray literature. Therefore, this guidance document should discuss and implement a methodology that the EPA can use to ensure incorporation of all available science, not just registrant studies.

¹²⁸ 2014 Bee Guidance.

IX. Conclusion

The petitioners look forward to EPA's response to this petition for amendments to 40 C.F.R. and the creation of a Soil Health Guidance document within in the next ninety days.

Sincerely,

A handwritten signature in cursive script, appearing to read "Nathan Donley".

Nathan Donley, Ph.D.
Environmental Health Science Director and Senior Scientist
Center for Biological Diversity

A handwritten signature in cursive script, appearing to read "Lori Ann Burd".

Lori Ann Burd
Environmental Health Program Director and Senior Attorney
Center for Biological Diversity

May 20, 2021

To:

EPA Administrator Michael Regan

OCSP Principal Deputy Assistant Administrator Michal Freedhoff

OPP Acting Director Edward Messina

Subject: Support for the Rulemaking Petition to Implement a Soil Health Endpoint in EPA's Ecological Risk Assessment for Pesticides

The undersigned 67 public health, environmental justice, environmental, human rights, chemical reform, faith, sustainable farming, healthy soil and farmer advocates urge the U.S. Environmental Protection Agency (EPA) to act swiftly in granting the Center for Biological Diversity and Friends of the Earth's 5/20/21 petition to include an analysis of soil ecosystems in its pesticide registration decision-making process. The petitioned for changes are necessary for the EPA to comply with its statutory requirements to only register pesticides if they do not cause any unreasonable risk to humans or the environment, as well as the agency's current guidance for assessing ecological risk.

Soils are incredibly complex and important ecosystems that are estimated to contain roughly a quarter of Earth's biological diversity. Thousands of species of soil invertebrates and microorganisms provide essential ecosystem services necessary for agricultural sustainability and ecological functioning, including carbon sequestration and resiliency in the face of global climate change.

It is estimated that 95% of the world's food comes either directly or indirectly from soil and that sustainable soil management could increase food production by 58%. Maintaining healthy soils is absolutely essential to ensuring robust and productive agriculture in the U.S. and a supply of healthy and nutritious food for future generations.

Pesticide toxicity to terrestrial invertebrates and soil application of pesticides have both been increasing over the last few decades, indicating that many soil organisms are under increasing threat from pesticide pollution. A recently published comprehensive review of pesticide impacts on soil found harm to beneficial invertebrates in 71% of cases. This finding demonstrates the urgent need to include a soil health endpoint in pesticide registration decisions.

Many species that spend some part of their life cycle in the soil, like ground beetles, ground-nesting bees and other terrestrial insects, have been precipitously declining in recent decades, and agricultural intensification and pollution are major driving factors. Worldwide, overuse of

chemicals in agriculture has been identified as the most impactful driver of soil biodiversity loss in the last decade.

At present, EPA assesses risk to all soil organisms using the European honey bee as a surrogate species. While it is critically important to have an adequate risk assessment for honey bees, using honey bees as a proxy does not reflect risk to soil microorganisms and invertebrates and does not address the indirect effects that loss of soil life can have on honey bees and other organisms. The agency must adopt a more comprehensive risk assessment framework that adequately values the ecological services of all life on Earth. A risk assessment based on the current knowledge of life systems must be adopted, protecting the environment and the food supply.

Our organizations fully support the soil health endpoint rulemaking petition that is in front of the EPA and urge the agency to immediately begin accounting for harms to soil organisms in its pesticide registration decisions even as it goes about granting the petition and incorporating the requested regulatory additions.

Signed,

American Sustainable Business Council

As You Sow

Bee Squared Apiaries

Beyond Toxics

Biodiversity for a Livable Climate

Boston Catholic Climate Movement

Catskill Mountainkeeper

Center for Food Safety

Central Maryland Beekeepers Association

Conservation Law Foundation

Cottingham Farm

Eastern Shore Food Hub

EcoHealth Network

Environmental & Public Health Consulting

Environmental Working Group

Fair Farms

Farm and Ranch Freedom Alliance

Farmworker Association of Florida

Georgia Organics

Global Evolutionary Alliance, LLC

Grantham Foundation

Green State Solutions

Hawai'i Alliance for Progressive Action

Healthy Soils Frederick of Frederick County, MD

Inga Foundation USA

Institute for Agriculture and Trade Policy

Kentucky Conservation Committee

Kiss the Ground 501c3

Land Core

Land Stewardship Project

Lexington Global Warming Action Coalition

Maryland Pesticide Education Network

Michael Fields Agricultural Institute

Mothers Out Front (National Leadership Team)

National Center for Appropriate Technology

National Latino Farmers & Ranchers Trade Association

National Sustainable Agriculture Coalition

Natural Resources Defense Council (NRDC)

New Growth Management

New Mexico Healthy Soil Working Group

Northeast Organic Farming Association of Massachusetts (NOFA-MA)

Northeast Organic Farming Association of New Hampshire (NOFA-NH)

Northeast Organic Farming Association of New Jersey (NOFA-NJ)

Northeast Organic Farming Association of New York (NOFA-NY)

Northeast Organic Farming Association of Rhode Island (NOFA-RI)

Northeast Organic Farming Association of Vermont (NOFA-VT)

Northeast Organic Farming Association-Interstate Council

Northern Plains Resource Council

Northwest Center for Alternatives to Pesticides

Ocean River Institute

Ohio Ecological Food and Farm Association

Organic Consumers Association

Pasa Sustainable Agriculture

People and Pollinators Action Network

Pesticide Action Network North America (PANNA)

Pollinate Minnesota

Pollinator Stewardship Council

Regeneration International

Rodale Institute

Safe Grow Montgomery

Savory Institute

Sierra Club

Slow Food California

Slow Food USA

Soil4Climate Inc.

Sonoma Safe Ag Safe Schools (SASS)

Women's Voices for the Earth